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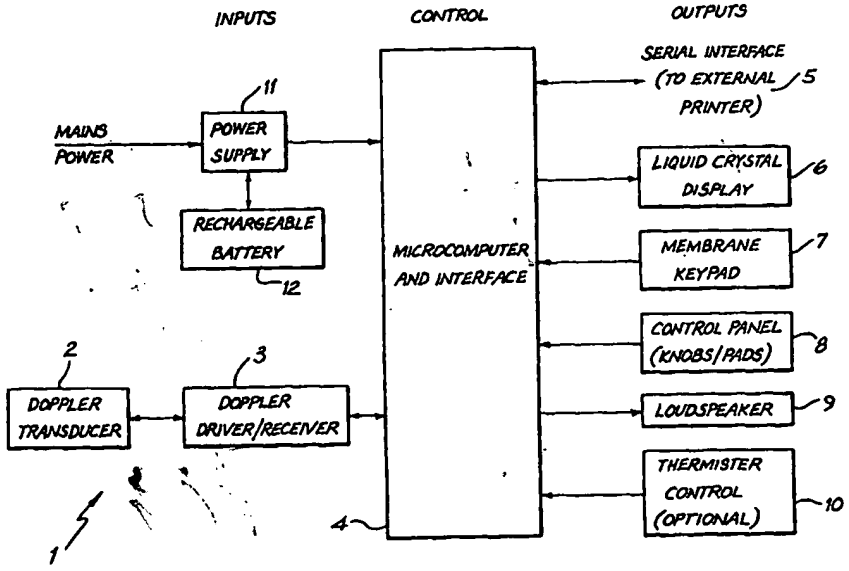

(57) Abstract

The present invention relates to a method and apparatus for monitoring haemodynamic function in animals and humans during anaesthesia and surgery. During anaesthesia and surgery the subject's haemodynamic, respiratory, neuromuscular and neurological functions are monitored as indicators of the condition of the health of the subject. Commonly, variations in blood pressure are used to imply corresponding variations in cardiac ouput, i.e. good blood pressure equals good cardiac output. The present invention utilises a device to monitor changes of blood flow in peripheral blood vessels of the subject as an indicator of cardiac output. This is believed to provide a much more accurate indicator.

METHOD AND APPARATUS FOR MONITORING HAEMODYNAMIC FUNCTION

The present invention relates to a method and apparatus for monitoring haemodynamic function in humans and animals and, particularly, but not exclusively, to a method and apparatus for monitoring haemodynamic function in humans and animals during anaesthesia and surgery, and its relationship to anaesthetic depth.

During anaesthesia and surgery on a human or animal subject, the subjects haemodynamic respiratory, neuromuscular and neurological functions are monitored as indicators of the condition of the health of the subject as anaesthesia and surgery progress. In general, as anaesthetic (depth) increases, haemodynamic, respiratory and neurological function are depressed or decrease (ie. there is a dose-dependent relationship). During any operation, it is important that adequate perfusion is maintained (ie. oxygenated blood reaches all vital organs including the brain, heart and kidneys). Tissue oxygen delivery is dependent on the level of perfusion or blood flow (cardiac output [CO]) and the amount of oxygen in the arterial blood (Arterial Oxygen Content, CaO_2). Haemodynamic function (causing blood flow to vital organs) is therefore carefully monitored and any changes which indicate that haemodynamic function may not be optimum will alert the anaesthetist who may adjust the anaesthetic dose to compensate ie., to vary the depth of anaesthesia by adjusting anaesthetic depth.

Traditional monitoring of haemodynamic function in anaesthetised patients undergoing surgery, in particular humans, is based on cardiac auscultation, an ECG (electro cardiogram) and blood pressure measurement. Cardiac auscultation will detect the rate of heart beats. The ECG directly monitors cardiac rhythm (electrical rhythm of the heart) and indirectly monitors the pulse rate (assuming the electrical rhythm causes an organised heart muscle contraction). Blood pressure monitoring devices measure

blood pressure, usually measure pulse rate and the information obtained is used by clinicians/anaesthetists to indirectly make inference about (estimate) haemodynamic function, i.e., cardiac output (total blood flow) and organ perfusion. The pulse rate, cardiac rhythm, blood pressure, and inference about haemodynamic functions provide the information necessary to give the anaesthetist an overall picture of haemodynamic function during anaesthesia and surgery.

This type of traditional monitoring of haemodynamic function, in particular the use of blood pressure monitors, is subject to a number of problems.

Indirect blood pressure monitors (systems using a pneumatic cuff and a method to detect the arterial pulse) are inaccurate in small animals, horses and human infants and automated devices can be expensive. Direct blood pressure monitors (systems using a catheter placed in an artery, connected to a pressure measuring device) are accurate but invasive, complex and expensive. Catheterisation of an artery is also NOT done without some risk of complication to the patient.

Further, the general perception in anaesthesia has been that good blood pressure equals good haemodynamic function. That is, if the blood pressure is good, it is taken as an indication that there is adequate blood flow to ensure perfusion of all the vital organs. During anaesthesia and surgery good blood pressure together with good results for the other indicators (cardiac rhythm, pulse rate, etc) has generally been taken to mean that everything is going well for the patient.

The majority of anaesthetic agents depress cardiac output in a dose dependent fashion. Generally, therefore, low blood pressure has been taken to indicate that anaesthetic dose should be lightened and high blood pressure that anaesthetic dose should be increased (although the other indicators also have a bearing on anaesthetic dose and the anaesthetist will take all

indicators into account before deciding on the appropriate action).

The present applicants have realised that blood pressure is not in fact as good an estimator of cardiac output or perfusion during anaesthesia and surgery as has traditionally been considered. Firstly, indirect measurement of blood pressure is inaccurate and secondly it is, in fact, frequently negatively related to total blood flow (cardiac output) and tissue oxygen delivery.

There is a recognised relationship between blood pressure, cardiac output and vascular resistance, as follows:

Cardiac Output = Blood Pressure (MAP-Right Atrial Press) ÷ Vascular Resistance.

One major problem with the usual assumption that blood pressure gives an indication of cardiac output is that none of the usual clinical measurements (auscultation, electrocardiogram, blood pressure) provide any information about vascular resistance.

During surgical procedures at usual anaesthetic levels, it is believed that the subjects body may still experience and respond to painful stimulation, although the subject is not consciously aware of the pain. The body, however, produces its standard sympathetic nervous system response to the painful stimuli, including catecholamine release, resulting in vasoconstriction. The applicants believe that such responses lead to increases in blood pressure during surgery being accompanied by a decrease in cardiac output. This is exactly opposite to the relationship between blood pressure and cardiac output which clinical anaesthetists have traditionally assumed. During painful surgery, therefore, rather than a direct positive relationship between blood pressure and blood flow there is believed to be a variable relationship which may even be in a negative direction.

Given the above observation, and also the fact that non-invasive blood pressure monitors are inherently

inaccurate, it is clear that, in anaesthetised patients undergoing surgery, blood pressure cannot be relied on as an accurate estimator of haemodynamic function.

The present invention provides a method of monitoring haemodynamic function in a human or animal subject during anaesthesia, comprising the step of monitoring blood flow in the subject during anaesthesia, to provide an indication of haemodynamic function and tissue oxygen delivery.

The method preferably finds most application during anaesthesia and surgery.

It is believed by the applicant that the monitoring of blood flow will provide a more accurate indication of changes in cardiac output than that inferred from monitoring blood pressure. It is thought that an increase in blood flow in a part of the body is more likely to indicate an increase in cardiac output, as compared to an increase in blood pressure, considering the limitations discussed above relating to using blood pressure as a cardiac output indicator during anaesthesia in surgery.

In anaesthesia and surgery, it is all important that haemodynamic function be maintained such that sufficient oxygenated blood reaches the vital organs, e.g. brain, liver, etc. Good cardiac output is a good indicator of whether there is sufficient blood flow to perfuse the vital organs, particularly during anaesthesia where patients usually breathe high inspired concentrations of oxygen.

Blood flow in an anaesthetised subject may be monitored in a number of ways. Cardiac output can be monitored directly, using indicator dilution techniques such as by the insertion of a pulmonary artery, thermo-dilution, cardiac catheter, for example. This method is intermittent, invasive, requiring cardiac catheterisation, which is not risk free and is not preferred, although insertion of such catheters provides an accurate measurement of total blood flow (cardiac

output). Indirect cardiac output or aortic blood flow measurement may also be made using 2 or 3-dimensional pulsed Doppler cardiac ultrasound, but with computer generated colour flow enhancement display this is very expensive, not accurate, technically difficult and is very sensitive to probe position, movement of the subject or the measuring probe such as occurs during surgical manipulation. In addition it requires a person to continuously hold the transducer on the body in a constant position.

Although the above techniques fall within the ambit of the present invention, they are not, therefore, necessarily preferred for routine clinical use, such as in anaesthetised subjects.

There are a number of devices on the market which the applicant has found could be adapted for monitoring blood flow in blood vessels or tissue beds, non-invasively, relatively inexpensively and generally being relatively non-movement sensitive. Such devices are particularly suitable for monitoring changes in blood flow in peripheral blood vessels, which the applicants believe will still provide a relatively good indication of changes in cardiac output. Indeed, the method of the present invention is preferably applied by monitoring changes in blood flow ("relative" blood flow), preferably in a peripheral blood vessel, to provide an indication of, preferably, changes in cardiac output. In other words, although direct measurement of cardiac output is within the ambit of the present invention, for practical clinical application, it is preferred to monitor blood flow in parts of the body where access is easier and, in particular, blood flow in peripheral blood vessels. It may be difficult to measure the actual blood flow in a peripheral blood vessel as, unless an invasive technique is used, the diameter of the peripheral vessel(s) can only be estimated. Changes in blood flow in peripheral vessel(s) can be monitored reliably, however. These

changes can be used to estimate changes in cardiac output (total blood flow) we believe, quite reliably. Changes in blood flow in the peripheral vessel during anaesthesia and surgery can, therefore, be utilised by the anaesthetist to adjust dose, eg. if blood flow in the peripheral vessel should fall, then the anaesthetist can imply corresponding falling cardiac output and can reduce anaesthetic dose to compensate (also taking into account other monitored factors, as discussed above). Changes in blood flow in the peripheral vessel, therefore, give a relative indication of changes in total blood flow (cardiac output).

Blood flow devices are known which detect blood flow in peripheral blood vessels of subjects, by employing an ultrasound sensor which uses the Doppler effect to detect either red blood cell motion or blood vessel wall motion. A signal is produced to simply indicate that motion is occurring (ie. the signal is either on or off/present or absent). An example of such a device is produced by Parks Electronics of Aloha, Oregon, USA. Presently, such a peripheral blood flow monitor is used together with a occlusive cuff and aneroid manometer to indirectly measure blood pressure. The occlusive cuff is tightened to the point that the monitor registers that there is no blood flow in a peripheral artery and the pressure is then read from the manometer. This method only allows the operator to obtain systolic arterial blood pressure. The Doppler monitor is therefore only used in this application to determine whether there is blood flow or whether there is not any blood flow, ie. "on" or "off".

A more advanced continuous wave Doppler device can print a pulsatile wave form based on the frequency and volume of the reflected Doppler, and calculate the peak and mean velocity of the blood flow. Such a device is manufactured by Hiashi Denki Company Limited in Japan (the ES-1000 SPM and ES-1000 SP).

As far as the applicants are aware, no such Doppler

monitor has been used for the purpose of monitoring haemodynamic function during anaesthesia. Indeed, none of the prior art devices are suitably adapted to be useful for use in such an application.

The present applicants have utilised a Doppler ultrasound device as a blood flow monitor, to provide a signal whose characteristics preferably varies depending on the amount of blood flowing in a particular peripheral artery, in order to provide at least a relative indication of changes in total blood flow (cardiac output). This device is used in one preferred embodiment of the method of the present invention.

Pulse oximeters measure the absorption of infra-red radiation by red blood cells in a peripheral vascular bed in order to determine the oxygen saturation of the blood. Since the amount of infra-red radiation absorption depends on the amount of blood, such a device may be adapted, in accordance with an embodiment of the present invention, to provide an indication of relative changes in blood flow in the peripheral vascular bed. This measurement of blood flow may be used as an indication of changes in total blood flow.

In yet a further embodiment, a colour chart may be utilised to estimate changes in blood flow in a tissue bed that has a high density of superficial blood vessels by reference to the colour of the mucous membrane in that tissue bed, eg. gums, tongue, lips, etc. Again, this provides a relative estimate of changes in total blood flow. Colour charts are designed by clinical observation of control subjects under various conditions and relating the observed colour to measurements of blood flow. In the limit, a colour chart is not even necessary to carry out the method of the invention, mere practiced observation of an appropriate tissue bed by a skilled anaesthetist could be used to estimate changes in mucous membrane colour and therefore in blood flow in that area and therefore provide a relative estimate of total blood flow.

The information obtained from monitoring blood flow will be used together with information from an electro cardiogram and measurement of blood pressure to provide a total picture of the haemodynamic condition of a subject during anaesthesia and surgery. This will give sufficient information for the anaesthetist to properly evaluate the haemodynamic condition of the subject and vary anaesthetic dose accordingly.

Preferably, where a blood flow monitor is used, the method of the present invention includes the further step of applying a regression analysis to the signal produced by the blood flow monitor. Preferably, the regression analysis applied involves the steps of monitoring in an animal or human subject either cardiac output, tissue O_2 delivery (in a subject under anaesthesia breathing a high inspired amount of O_2, arterial oxygen content is generally constant as changes in tissue oxygen delivery reflect changes in cardiac output) against the signal from the blood flow monitor. The data can be used to produce a plot which can be described by regression analysis. The regression equation can be used to calibrate the actual output of the blood flow monitor to provide a more accurate relative indication of CO or tissue oxygen delivery.

Preferably, the method also includes the further step of making a further adjustment to the signal output by the blood flow monitor by applying changes in heart rate as a co-variant factor. This has been found to further improve the estimate of CO of tissue oxygen delivery.

The present invention further provides a device for monitoring haemodynamic function in a human or animal subject during anaesthesia, comprising a blood flow monitor arranged to monitor blood flow in the subject during anaesthesia, to provide an indication of cardiac output.

The device is preferably arranged to provide an indication of changes in blood flow during anaesthesia,

preferably in a peripheral blood vessel. Changes in blood flow in the peripheral vessel can preferably be used to provide a relative indication of changes in cardiac output. By "changes in blood flow" is meant changes of degree, not merely presence or absence of flow.

Although direct cardiac output monitors, such as systems using thermo-dilution catheters which are insertable into the pulmonary artery or aorta, or 2 or 3-dimensional pulsed Doppler ultra-sound devices, do fall within the ambit of this invention, preferred blood flow monitors are able to non-invasively monitor blood flow in peripheral blood vessels and provide an output signal who's characteristics vary depending upon actual blood flow in the peripheral vessel(s) being monitored. As discussed above in relation to the previous aspect of the present invention, changes in blood flow in a peripheral vessel provides a relative indication of changes in total blood flow (cardiac output). Preferably, the device comprises a display or indication means, and means for receiving the signal from the blood flow monitor and processing it to drive a display or other indication means to provide an indication of blood flow, preferably changes in blood flow, which can be monitored by the clinician, such as an anaesthetist.

In a preferred embodiment, the device may be pre-calibrated for a particular subject by, firstly, taking the strength of the blood flow signal from the blood flow monitor when the patient is at rest prior to induction of anaesthesia and surgery and, then using an occlusive cuff to shut off blood flow to the peripheral vessel, obtaining a zero signal. The display on the device can then preferably be set between the upper rest resting blood flow rate and the zero blood flow rate. The device preferably includes an alarm warning indication means to provide an indication of an alarm situation, if the blood flow in the peripheral vessel drops below a certain pre-determined amount.

The device is preferably adapted to give an output which is particularly designed to be useful for an anaesthetist monitoring a subject under surgery. The display preferably provides indications of changes in blood flow in the patient and, preferably, an alarm is provided to sound or provide an indication of an alarm condition when a blood flow change occurs which indicates that a person is either anaesthetised too deeply or not deeply enough. The display may be graded with markings indicating the changes in blood flow in relation to anaesthetic conditions, i.e., too much anaesthetic, too little anaesthetic, etc.

The device is also preferably arranged to apply an adjustment factor to the blood flow monitor signal, the adjustment factor being based on a regression analysis of actual subjects. The device is also preferably arranged to provide a further adjustment to the signal by taking a co-variant as an input to adjust the signal, and, preferably, the co-variant is heart rate. The adjustment preferably results in an improved output signal.

The blood flow signal may be derived from a pulse oximeter, Doppler monitor, as discussed above.

In an alternative embodiment, the blood flow monitor may comprise a colour chart including coloured patches to be compared with an area of the body of the subject, eg. the lips or tongue. The colour chart would be pre-determined for an "average" subject of the particular animal type (or human being) to give an indication of blood flow depending upon the colour of the body part at the time.

A blood flow monitor and method in accordance with the present invention may have applications other than during anaesthesia. For example, a device which is arranged to monitor changes in blood flow in peripheral vessels or peripheral tissue beds may have application in cardiac stress testing, and other applications.

From a further aspect the present invention provides

a device for monitoring haemodynamic function in a human or animal subject, comprising a blood flow monitor arranged to monitor changes in blood flow in a peripheral vessel or tissue bed, to provide an indication of changes in cardiac output.

The present invention further provides a method of monitoring haemodynamic function in a human or animal subject, comprising monitoring changes in blood flow in a peripheral vessel or tissue bed, to provide an indication of changes cardiac output.

The device and method of this aspect of the present invention may include any or all of the features of the device and method discussed above.

Features and advantages of the present invention will become apparent from the following description of embodiments thereof, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a schematic block diagram of a device in accordance with one embodiment of the present invention;

Figure 2 is a schematic perspective view of a external appearance of a device in accordance with the embodiment of figure 1;

Figure 3 is a view of an example operating display of the device of figure 1, for a human subject during anaesthesia in surgery;

Figures 4 through 7 show various displays of the programming (set up) and alarm setting functions, displayed as for animal operation;

Figure 8 is a view of a "colour chart" in accordance with an embodiment of the present invention; and

Figure 9 is an example plot of cardiac output or tissue 0_2 delivery against "perfusion index" to demonstrate how regression analysis is to be applied to the output signal of a blood flow monitor in accordance with an embodiment of the present invention.

A device in accordance with an embodiment of the present invention, for use with a method in accordance

with the present invention, is illustrated in figures 1 through 7. The device can be used as discussed in the preamble, to monitor changes in blood flow in a peripheral blood vessel of a human or animal subject during anaesthesia and surgery. This gives an indication of relative changes in total blood flow (cardiac output) as one of the indicators for enabling the anaesthetist to monitor the subjects haemodynamic condition and suitably adjust anaesthetic dose. Monitoring peripheral blood flow to provide an indication of changes in cardiac output, as opposed to using blood pressure, runs contrary to anaesthesia practice over the past one hundred years where blood pressure is used in surgery to indicate changes in haemodynamic function or cardiac output. As discussed above, the present applicants believe that, because of responses to painful stimuli during surgery, blood pressure is neither a reliable or positive indicator of changes in cardiac output. They believe that either monitoring of total blood flow or, as in the preferred embodiment of the invention, monitoring of changes in blood flow in a peripheral artery during anaesthesia in surgery, will provide a much better positive indication of relative changes in total cardiac output.

The method of monitoring haemodynamic function during anaesthesia and surgery in accordance with the preferred embodiment of the present invention, also preferably includes the steps of monitoring blood pressure, using standard equipment, monitoring ECG, using standard equipment and monitoring respiration using an airway thermistor. The heart rate may be monitored using the ECG device. The pulse rate may be monitored using the device in accordance with the present invention, being determined from the peripheral blood flow. These parameters, together with blood flow, provide the total "picture" required by the anaesthetist to enable monitoring and adjustment of anaesthetic dose to ensure the haemodynamic health of the subject.

Figure 1 is a functional block diagram showing components of an ultrasound based device for monitoring blood flow, in accordance with an embodiment of the present invention. The device, generally indicated by reference numeral 1, comprises a Doppler transducer 2 for monitoring blood flow in a peripheral blood vessel of a human or animal subject. In operation, the transducer will be affixed to the appropriate body part of the subject eg. placed distally on the wrist or ankle of a human being, or where an animal is the subject, on the tail. Note that as an alternative to a Doppler transducer 2, a pulse oximeter adapted to monitor blood flow could be used as the blood flow detector (transducer). In fact, any device which is capable of detecting blood flow, in the preferred embodiment in a peripheral vessel, could be used.

Note that a further alternative, in accordance with an alternative embodiment of the present invention, is to use a device such as a pulse oximeter in addition to using the Doppler transducer 2 to monitor the changes in blood flow. The pulse oximeter is, in accordance with this embodiment, adapted to monitor blood volume in a peripheral tissue bed (rather than oxygen saturation which is usually constant during anaesthesia where patients inspire high concentrations of oxygen) and this may be used to improve the estimate of changes in blood flow or to enable estimation of changes in vascular resistance. In this alternative embodiment, the device of figure 1 would also include a sensor and a pulse oximeter device providing an input about changes in tissue blood volume to the micro computer 4 for processing together with the perfusion input from the Doppler device. The following description, however, relates to an embodiment which employs a Doppler monitor only.

In this embodiment, a continuous wave Doppler driver/receiver 3 is connected to the Doppler transducer for transmitting and receiving ultrasound signals

therefrom. A microcomputer and interface 4 is arranged to process the signal from the receiver 3, and drive the LCD display 6 to produce an output indicative of changes in cardiac output (substantially equivalent to tissue oxygen delivery under high inspired concentrations of O_2). It also controls and/or responds to the other peripherals, as follows:

a serial interface 5 to an external printer;

a liquid crystal visual display 6;

a membrane keypad 7;

a control panel 8;

a loud speaker 9; and

a thermistor controller 10 for controlling a airway thermistor (not shown).

Power is provided from the mains via a power supply regulator 11, which is also provided with a back-up rechargeable battery 12, in case of failure of the mains.

In operation, the microcomputer controller 4 operates to process the signal from the Doppler transducer 2 to determine changes in the blood flow rate in the peripheral vessel and to control the liquid crystal display 6 to provide an indication, preferably graphical indication, of the instantaneous relative cardiac output at any time during anaesthesia and surgery. It is preferred to give an output of relative cardiac output, rather than attempting to produce an output indicative of actual cardiac output. Attempting to obtain a measurement giving actual cardiac output is very difficult because a) vessel diameter is required or b) it assumes that changes in blood flow or vessel diameter in one vessel similarly reflect changes in the whole animal. Monitoring changes in blood flow to provide an output relative to a reference, such as the signal output by the blood flow monitor when the patient is at rest prior to anaesthesia and surgery, is much more convenient, and provides sufficient indication to the anaesthetist to guide him to control anaesthetic depth. The loudspeaker 9 is

controlled by the controller 4 to provide an audible pulse signal and alarms should the blood flow fall below or rise above pre-set levels. Preferably, the display 6 also provides a visual alarm indication. The control panel 8 can be used to pre-set the blood flow display and alarm limits, depending upon, for example, the size of the subject and the species of the subject. It is envisaged that a device would be provided suitable for operation on a human subject and a separate device suitable for operation on animal subjects, the animal subject device preferably being adapted for use with a number of animal species, control limits being pre-set for species and animal size by the control panel 8. The microcomputer and interface 4 is arranged to process the Doppler signal output to give an indication of blood flow changes based on the strength of the signal.

Figure 2 shows the external appearance of an example device 1. Equivalent items to figure 1 are given the same reference numerals. The entire device 1 is housed within a robust housing 13. Brackets 14 are provided to hold a reference manual giving operating instructions on the device 1. The device is mounted on rubber feet 15 and has a carrying handle 16. A plug 17 is provided for connection to a mains power supply.

In operation, before a subject is anaesthetised, the Doppler transducer (sensor) 2 is positioned on the skin surface, overlying a peripheral artery such as located in the human forearm at the level of the wrist (radial or ulna artery), on the plantar surface of the foot of a dog or cat (pedal artery) or on the ventral surface of the tail (coccygeal artery). The device is attached to the subject at rest while conscious and a flow rate determined. The control pad 8 is then used to set a "base line flow" rate and a base bar (reference number 20, figure 3) will appear on the operating display. The base bar will be used as a reference by the anaesthetist as the "normal" flow rate of the conscious resting subject (ie.

prior to induction of anaesthesia). As an alternative, the device may also be arranged to store a series of "standard" base bars, being default settings for a particular animal species/size of animal. This would be necessary for animals which may not tolerate attachment of the transducer while conscious. For a human subject, however, it is preferable to pre-set the levels and the display by monitoring of the individual subject.

Figure 3 shows an example operating display for a human subject during anaesthesia and surgery. The left hand side of the display, indicated by reference numeral 21, is taken up by a bar graph which graphically continuously indicates peripheral blood flow rate based on the signal obtained from the peripheral vessel, processed by the controller 4 to provide the display. The base bar 20 is permanently in place on the graphical display and is pre-set by monitoring the flow rate of the conscious subject at rest, prior to the induction of anaesthesia. All flow rates and flow alarms are determined relative to this base bar 20. A high limit bar 22 and low limit bar 23 are also displayed. These can either be pre-set by the anaesthetist or pre-stored in memory to automatically be displayed depending upon the set base bar level and other subject factors, eg. weight, age, etc. For example, appropriate limits could be determined by clinical trials and then stored in the memory of the device.

A moving flow marker 24 is also displayed. This shows the actual real-time flow rate (relative to the base bar). It is this marker 24 that the anaesthetist will watch carefully to obtain an indication of changes in haemodynamic function. Preferably, the flow marker is arranged to flash. Should the rate fall to the lower limit bar 23 or rise to the high limit bar 22 an audible alarm will sound and the numeric flow display 26 will flash. The anaesthetists attention will thus be drawn to the alarming level of perfusion or blood flow and appropriate action can be taken (eg. altering anaesthetic

dose, administration of IV fluid, inotropic drugs etc.). Note that it is unlikely during appropriate levels of anaesthesia during surgery in normal, healthy patients that blood flow will ever rise much above the base bar. This is because standard anaesthetics tend to depress (rather than stimulate) cardiac output in a dose dependent fashion. Such a monitoring device can also be used for monitoring haemodynamic function during critical care such as post cardiac surgery. On this point, a novel device such as this is likely to provide precise clinical data on the effect of anaesthetics and surgical manipulation on peripheral blood flow in humans and animals. However, there are applications of this device, such as cardiac stress testing (treadmill testing) of conscious humans or race horses, where blood flow could increase above the base line measurement.

Referring again to figure 3, the controller 4 also determines the pulse rate of the subject from the Doppler flow signal. This is displayed in the top right hand portion 25 of the display 6. The anaesthetist can also therefore view pulse rate, at a glance. The bottom right hand corner of the display 26 displays the actual (instantaneous) peripheral blood flow rate in alphanumeric.

Should the probe signal change caused by transducer or skin movement relative to the artery or loss of acoustic coupling or otherwise malfunction, a "probe error" display will flash 27.

Switching the device on and taking no further action defaults the screen to the monitoring display (figure 2). All input and control of the device is set by rotating knob 80 (figure 2) to select function or value and pressing enter to accept function or value.

Upper and lower limit thresholds may also be set for pulse rate, such that if the thresholds are reached audible alarms/visual alarms are provided. A breath to breath audible output and a numeric display of respiratory

rate, may also be provided if an airway thermistor is employed.

Figures 4 through 7 show examples of screen displays which may appear during initial set up of the apparatus prior to operation on a human or animal subject. The example screens are based on the device as designed for animal use. This is generally the same as what would appear in the device as designed for human subjects, except that it is envisaged that there would be no screen for default species settings (figure 5) although default settings based on body size could be introduced. Alternatively, all the settings for the alarm function could be entered manually (figure 4). After selecting either the default settings (figure 5) or entering the alarm settings manually (figure 4), the device will then display the result and settings as selected (figure 6) before reverting to the "running" display associated with the continuous monitoring function (a running display is shown in figure 3 for a human being, but a similar display would be shown for animal).

The boxed items of display (figure 4) ("Run", "Pause" etc) are what can be selected by turning the knob 80. A selected function displays as inverse display (ie. white letters on black background). Depressing the knob will then cause the numerical value to increase in magnitude to a maximum number. Subsequently turning the knob by 10° will move the selection to the next boxed item in a left to right, top to bottom flow with wrap-around at bottom. Turning the knob counter clockwise will reverse the selection highlighting.

Figure 4 shows a typical data entry display for manual entry of the alarm settings, which enables entry of pulse rate high/low limits and flow rate high/low limits ie. minimum, base and maximum levels for each item. These values can be set manually based on the preference/clinical experience of the anaesthetist. Alternatively, selection of alarm limits may be based on

default settings as shown for animals.

Figure 5 shows a display for default settings which can be selected, which will be based on clinical trials for the particular species/weight of animal (Note that manually five entered default settings may be stored by the user in memory.) Figure 6 illustrates the screen with the default settings which were either entered manually (figure 4) or selected (figure 5). Devices may obviously be designed with different default settings for different species and animal sizes, depending upon application.

Figure 6 is a diagram of the entered/selected alarm setting display, also showing the rest of the control panel from figure 2, incorporating screen selection knob 80, mode button 31, enter button 32 and on/off switch 33.

For this example (10-20kg dog) using figure 6 "enter" can be pressed while the selection knob is set on "Animal Class" to display the Animal Class display from figure 5. A 10-20kg dog will be class "3", the knob is turned 10° clockwise to highlight the numerical animal class function number 3 which results in the various high/low default limits shown in figure 6. Enter button is then pressed which now selects the default settings (for class number 3) and changes the display screen to figure 6. Turning the knob 5° will increment by one value resulting in the display value being 1. Thus turning the knob to approximately 55° clockwise will set the value to 11 (a 15kg dog). The knob can be rotated counter-clockwise to decrement the values. Again the "enter" button is pressed which records and accepts the value. At this point all the values on the Data Enter display will change to the default values for a 15kg dog. The highlighted box will move to the RUN box assuming the "enter" button will be pressed to accept all the default values and change the display to Figure 7 - If a Run Display of particular value is to be changed, eg. warning tone to OFF, the knob is turned either clockwise or counter-clockwise to the desired box. Pressing enter will toggle the value (to

on/off etc) and move the selection to next value (left to right, top to bottom). When all values on the Data Enter display are set and RUN is entered, the display changes to the RUN display.

In the PAUSE mode (Figure 7), the display will be inverse. All Data Enter values will be displayed on the RUN display format.

The Doppler sensor is secured with the animal sedated.

RUN is selected by turning the knob counter-clockwise approximately 10° and "enter" button pressed. The monitor will now start to function, updating the display approximately every 15 seconds, showing heart rate, flow, and moving the flow marker above or below the base value. At any time during operation the knob can be turned to highlight any value on the run display.

During the procedure, the base value may need to be adjusted. Such as with re-positioning the patient for surgery. Turn the knob to highlight the base value eg 2.0 Figure 3, press enter, turn the knob (clockwise or counter-clockwise) to display the desired base flow, then press enter. The monitor will accept the new base flow number and readjust the High/Low limit bars.

With regard to the embodiments discussed above, the output signal from the Doppler transducer is a signal the amplitude and/or frequency of which varies depending upon the rate of blood flow in the peripheral vessel being monitored. As discussed above, the signal can therefore be processed by the micro computer 4 to control a display to give an output indicative of changes in total blood flow (haemodynamic function), as the changes in blood flow in the peripheral vessel correlate with changes in total cardiac output (CO). In a clinical situation, such as during anaesthesia in surgery, the accuracy of this correlation is important, i.e., it is important that the displayed changes correlate well with the actual changes in cardiac output or tissue oxygen delivery. If the

display gives an inaccurate reading, particularly in the critical range (i.e., in the region of the alarm levels) then information given to the anaesthetist can be misleading and ultimately lead to a dangerous situation.

The present applicants have found that the accuracy of the correlation between the changes in the output signal from the Doppler transducer and changes in cardiac output can be much improved by further processing of the signal to adjust the signal by a factor which is based on regression analysis of actual experimental subjects. They have also found that the correlation can be even further improved by adjusting the processed signal by employing a co-variant factor, in the preferred embodiment being heart rate. Adjustment of the signal using these factors preferably leads to a more accurate output and the microprocessor is preferably arranged to process the signal from the Doppler transducer by including adjustments based on these factors.

Figure 9 is a schematic plot of "Perfusion Index" in relation to cardiac output (CO) or tissue oxygen delivery, for a notional experimental subject, to illustrate how regression analysis may be applied in accordance with this embodiment of the invention. Perfusion Index is a term the applicants have chosen to represent the processed output of the Doppler device (or where another device is being used to monitor blood flow, the output from that device). The processed signal from the Doppler device, which is a voltage output proportional to doppler frequency change, whether it be amplitude or frequency, provides an output known as the Perfusion Index. Ideally, this output will be directly proportional to cardiac output or tissue oxygen delivery (curve A of figure 9). During anaesthesia, high inspired amounts of oxygen are applied so that the arterial oxygen content is relatively constant. Changes in cardiac output can be taken to be substantially the same as changes in tissue oxygen delivery, therefore, in these circumstances.

The ideal, unfortunately, is not the case. From experiments with subjects, however, it is possible to plot Perfusion Index against CO or tissue oxygen delivery, by monitoring cardiac output with another device arranged to directly monitor cardiac output, and by applying a device such as a Doppler monitor to monitor "Perfusion Index", on an experimental subject, to give a realistic plot, plot A in figure 9. The equation for the curve is:

$$y = ax + b$$

where y is in this case cardiac output or tissue oxygen delivery, x is Perfusion Index, a is the slope and b is the intercept (see figure 9).

By adjusting the output of the Doppler device by modifying it by a factor corresponding to a and b, i.e., modifying it by using a regression analysis employing a experimental subject, a more accurate correlation of Perfusion Index (i.e., the new adjusted Perfusion Index) with cardiac output or tissue oxygen delivery can be obtained. In the preferred embodiment, therefore, the micro computer 4 is arranged to modify the output of the Doppler receiver 3 by a factor relating to the regression analysis. This has been found to provide a much improved output, i.e., a more accurate indication of the cardiac output.

In application, therefore, regression analysis is carried out by a monitoring perfusion index against cardiac output or tissue oxygen delivery for a plurality of subjects. The results of the regression analysis are then used to calculate a weighting factor to be applied to the output from the Doppler monitor, by the device in accordance with the embodiment of the present invention, in order to adjust that output to create a more accurate output indicative of cardiac output or tissue oxygen delivery. In the example given in figure 9, a and b are calculated and y with the new adjusted output, is produced in accordance with the formula $y = ax + b$.

Note that tissue oxygen delivery = tissue blood flow

(cardiac output) x arterial oxygen content.

A further improvement to the correlation of Perfusion Index to cardiac output can be made by further modifying the output signal from the Doppler transducer by making an adjustment for a co-variate factor.

Cardiac output = heart rate x stroke volume.

Cardiac output also = mean arterial pressure/vascular resistance.

There are therefore a number of variants which influence cardiac output and which may also determine the accuracy of an output signal from the Doppler monitor. The applicants have found that, in patients anaesthetised for surgery, including a co-variate factor based on heart rate also results in an increase in the accuracy of the final output of the device. A co-variate factor relating to mean arterial pressure does not improve the output and in fact degrades it.

Preferably, therefore, in accordance with the preferred embodiment of the invention, the output of the Doppler monitor is also adjusted by applying a co-variate factor, based on the heart rate of the patient. Again, a number of experimental subjects are monitored to see what variation of the output of the Doppler monitor (perfusion index) occurs with pulse rate. A weighting factor is then applied to the output from the signal in accordance with detected heart rate for a patient, to further improve the response of the device.

A further modification which may be made to the device is to process the output to provide an indication of the "trend" of the output and also provide a display of the trend. All measurements are stored periodically, for example every one to five seconds, and a display which gives the direction that the output is taking, i.e., either up or down, is provided for the anaesthetist. This "trend" display can be useful in anaesthesia, and will generally provide more direction to an anaesthetist as far as anaesthetic dose required is concerned, than a straight

forward "number" display not indicating any trend.

As discussed above, the preferred Doppler device to be used with the present invention is a continuous wave Doppler. These are preferably cheap, easy to build and portable. In operation, the ultra sound beam is transmitted from one crystal and the reflected wave received by another. The change in frequency of the reflected signal is in part due to the velocity of the red blood cell flow. The change in the amplitude of the signal depends on the vessel, distance and tissue density differences.

Vessel wall motion alters the high amplitude, of the signals which influences the shape of the amplitude/time spectrum of the reflected wave. This problem can be minimised by using Doppler crystals with higher sound frequencies (8 to 10 MHz). In addition use of front end clutter filters designed to optimise the illumination of reflected sound from skin, subcutaneous tissue and fat can be employed, and this is preferred. Since the amplitude and time lay of the reflected noise depends on the depth and size of the blood vessel being analysed, the filters are preferably specific for either body size (e.g., adult human, child or neonate) or species (e.g., cat, dog, horse). A toggle switch preferably enables the operator to select the desired clutter filter (not shown in the figures).

The change in time difference between the reflected signal from the proximal and distal wall of the blood vessel can be analysed and will indicate changes in blood vessel diameter. An estimate of blood vessel diameter combined with the estimate of velocity of blood flow, can be used to give index of blood flow, which can be modified in accordance with the factors discussed above to give the desired output (perfused index) which accurately correlates with Cardiac Output. As discussed in the preamble of the specification, other devices which are capable of monitoring blood flow could be used instead of

continuous wave Dopplers.

As discussed above, a pulse oximeter may also be used to provide a monitoring device in accordance with the present invention.

Pulse oximeters are currently designed to measure the transmission of red and infra-red light from haemoglobin of the arterial blood and estimate the arterial oxygen saturation. However, changes in the reflective wavelength of the light from the tissue bed depend on:

A. Changes in the oxy-haemoglobin level.

B. Changes in the total mass of tissue including red blood cells.

Once a pulse oximeter is functioning on a patient, it assumes that the background tissue and blood "mass" is constant (fixed), it focuses on the pulsatile part of perfusions or blood flow wave form and therefore assumes that changes in the wavelength of the light are due to changes in oxygenation.

Typically during anaesthesia, patients breath high inspired concentrations of oxygen. Therefore, changes in light absorption are far more commonly due to changes in the mass of red blood cells (i.e., the assumed to be constant light absorption) than to changes in arterial oxygenation.

To modify a pulse oximeter, we need to work form the principle that using two light wavelengths (one in the visible red spectrum and one in the infra-red spectrum): at the isobestic wavelength, the absorbing power of oxyhaemoglobin in the reduced haemoglobin is the same. Therefore total absorbency depends only on the sum of the two and not the state of oxygenation. Therefore the total absorbency depends only on the total amount of blood present. As tissue blood flow increases or decreases, the total absorbency at the isobestic point will change and this can be used to give a measure of the relative change in blood (mass) flow in the tissue bed. Such a device can therefore be used to monitor changes in blood flow in

peripheral tissue beds.

Electromagnetic flow meters have been designed to be surgically implanted around large blood vessels such as the aorta and renal artery. It is possible that such a device may be adapted to be placed around a peripheral tissue bed, such as a finger or tail, to provide an indication of relative changes in blood flow. This may not be accurate, however.

There is no reason that an electromagnetic flow meter could not be used in the present invention, by implantation of a cuff type flow meter around a blood vessel. This is, however an invasive technique, and although it falls within the scope of the present invention it is not preferred.

Other available devices which could be adapted in accordance with the present invention are non-invasive optical flow meters. These devices measure the absorption characteristics of light scattered by blood flowing through tissues such as skin surface, detecting this reflected light, analysing the frequency of the wave forms to obtain the mean peak light frequencies in estimating blood flow. Problems with this approach are that the device only measures very superficial (i.e., skin surface) blood flow, which during anaesthesia is altered by vaso constriction such as caused by changes in body temperature. The device is also subject to movement artefacts/vibrations such as caused by patient positioning, movement by surgical manipulations, restorations, vibrations from re-circulating water beds, etc. It is therefore difficult to get a continuous measure from a wave (pre-anaesthesia) through to anaesthesia when positioned for surgery.

Further, the signal requires considerable damping to get a stable measurement, which sacrifices the accuracy of the "real time" measurement. It also relies on estimating the Doppler signal change in the scattered light to obtain the peak frequency and fails to measure perfusion of

deeper tissues. Nevertheless, although not preferred, it is quite possible that such a device could be used in the present invention.

The above description is of a relatively sophisticated device which can be used with the method in accordance with the present invention. As discussed in the preamble, a primitive device, in the form of a "colour chart" can also be used. Colours indicating various flow rates would be established by clinical trials for various species in order to produce the colour chart. An anaesthetist will then have reference to the colour chart and compare with the colour of the part of the body concerned such as the oral mucosa, in order to monitor flow rate in the subject. An example colour chart is schematically illustrated in figure 8.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS:

1. A method of monitoring haemodynamic function in a human or animal subject during anaesthesia, comprising the step of monitoring blood flow in the subject during anaesthesia, to provide an indication of cardiac output.

2. A method in accordance with claim 1, wherein the step of monitoring blood flow comprises the step of monitoring blood flow in a peripheral blood vessel.

3. A method in accordance with claims 1 or 2, wherein the step of monitoring blood flow comprises monitoring changes in blood flow to provide an indication of changes in cardiac output.

4. A method in accordance with claims 1, 2 or 3, wherein the step of monitoring blood flow is carried out non-invasively.

5. A method in accordance with any one of the preceding claims comprising the further step of setting a predetermined limit for blood flow rate, which limit indicates an alarm condition should it be reached.

6. A method in accordance with any preceding claim, comprising the step of pre-setting a base level for blood flow rate being the indicated flow level of the subject at rest before anaesthesia, or being an average flow level for the particular type of subject prior to anaesthesia.

7. A method in accordance with any preceding claim, wherein the step of monitoring blood flow includes employing a device which produces a signal which varies with variations in blood flow, and processing the signal to produce an output providing an indication of cardiac output.

8. A method in accordance with claim 7, wherein the step of processing the signal includes the step of modifying the signal by an adjustment factor obtained by a regression analysis of a human or animal subject.

9. A method in accordance with claim 7 or 8, wherein the step of processing the signal comprises modifying the signal by an adjustment factor obtained from

a co-variate parameter.

10. A method in accordance with claim 9, wherein the co-variate parameter is heart rate.

11. A method in accordance with any preceding claim, comprising the step of applying the Doppler effect to monitor blood flow.

12. A method in accordance with any one of claims 1 to 10, comprising employing an infra-red blood flow sensor (eg. pulse oximeter) to monitor blood flow.

13. A method in accordance with any one of claims 1 to 10, comprising employing an electromagnetic flow meter to monitor blood flow.

14. A method in accordance with any one of claims 1 to 10, comprising the step of employing a colour chart to monitor blood flow, and comparing the colour of a predetermined part of the subjects body with the colour chart to provide an indication of cardiac output.

15. A method in accordance with any one of claims 1 to 10, comprising the step of monitoring the colour of a part of the subjects body in order to monitor blood flow.

16. A method in accordance with any one of claims 7 to 13, wherein the signal is processed to produce a display which indicates the trend of the cardiac output.

17. A device for monitoring haemodynamic function in a human or animal subject during anaesthesia, comprising a blood flow monitor arranged to monitor blood flow in the subject during anaesthesia, to provide an indication of cardiac output.

18. A device in accordance with claim 17, the blood flow monitor being arranged to monitor blood flow in a peripheral blood vessel of the subject.

19. A device in accordance with claim 17 or 18, the blood flow monitor being arranged to monitor changes in blood flow to provide an indication of changes in cardiac output.

20. A device in accordance with any one of claims 17, 18 or 19, the blood flow monitor being arranged to

produce a signal which varies with changes in blood flow and a device further comprising a processing means for processing the signal to produce an output providing an indication of cardiac output.

21. A device in accordance with claim 20, wherein the processing means is arranged to adjust the signal by an adjustment factor obtained from regression analysis of a human or animal subject.

22. A device in accordance with claim 20 or claim 21, the processing means being arranged to adjust the signal by an adjustment factor obtained from a co-variate.

23. A device in accordance with claim 22, wherein the co-variate input is heart rate.

24. A device in accordance with any one of claims 17 to 23, wherein the blood flow monitor comprises a Doppler sensor adapted to monitor blood flow changes.

25. A device in accordance with any one of claims 17 to 23, wherein the blood flow monitor comprises an infra-red sensor such as a pulse oximeter adapted to monitor blood flow.

26. A device in accordance with any one of claims 17 to 23, wherein the blood flow monitor comprises an electromagnetic flow meter.

27. A device in accordance with any one of claims 20 to 26, comprising a display, the processing means being arranged to control the display to give an indication of the cardiac output in the subject.

28. A device in accordance with claim 27, being arranged to display a base reference value to compare with an indicated value during anaesthesia during surgery.

29. A device in accordance with claim 27 and claim 28, being arranged to display trend analysis for cardiac output, showing the trend of the cardiac output.

30. A device in accordance with claims 17 to 23, wherein the blood flow monitor comprises a colour chart which the anaesthetist can compare with the colour of a predetermined part of the body of the subject.

31. An infra-red sensor such as a pulse oximeter adapted to provide signals indicative of the rate of blood flow in a peripheral vessel of a subject.

32. A method of monitoring haemodynamic function in a human or animal subject during stress testing or during critical care (such as post surgical care) comprising the step of monitoring changes in blood flow in the subject during stress testing or critical care.

33. A method in accordance with claim 32, wherein the step of monitoring changes in blood flow comprises the step of monitoring changes in blood flow in a peripheral blood vessel.

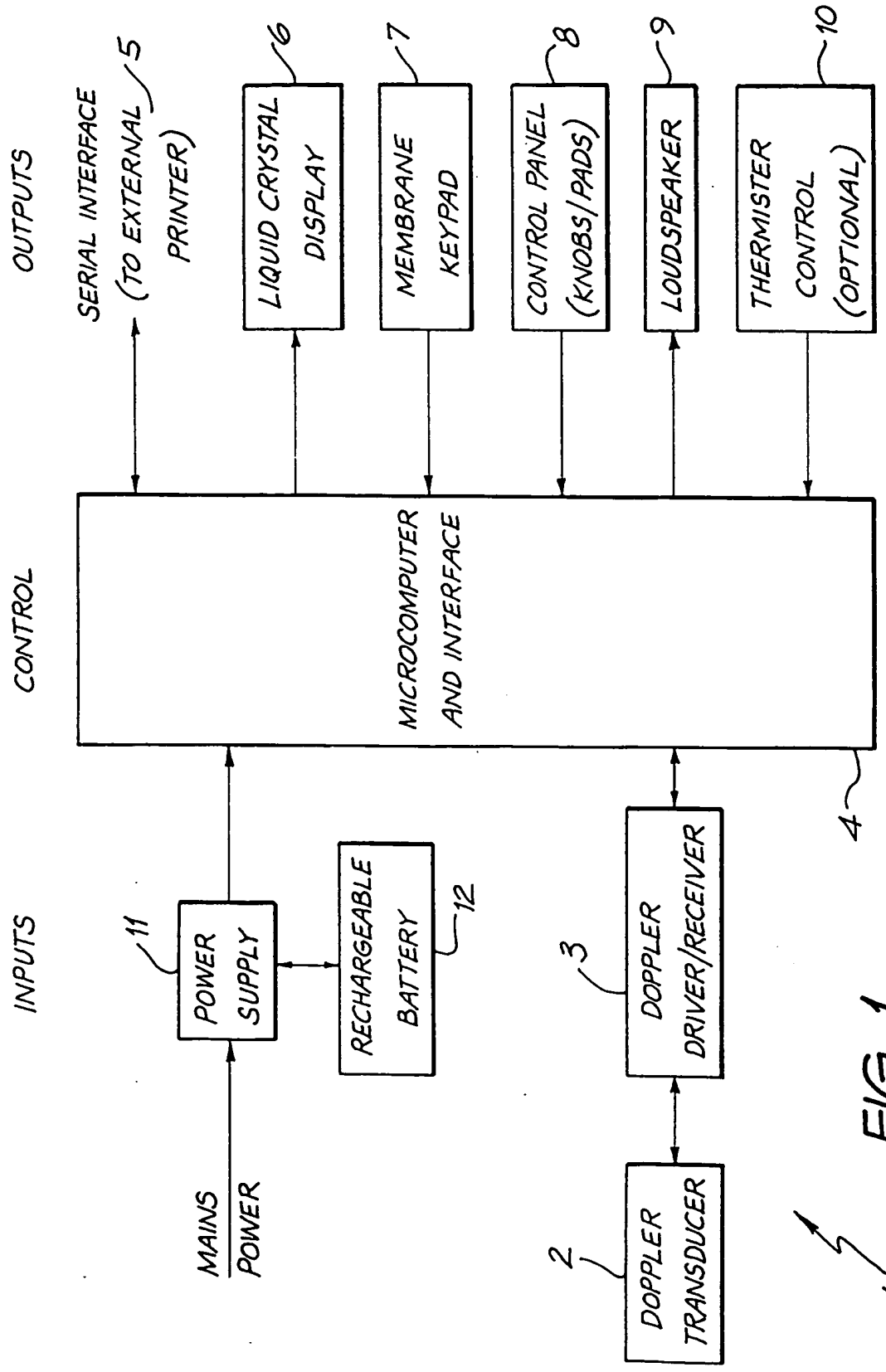
OUTPUTS
SERIAL INTERFACE (TO EXTERNAL PRINTER)
5
LIQUID CRYSTAL DISPLAY
6
MEMBRANE KEYPAD
7
CONTROL PANEL (KNOBS/PADS)
8
LOUDSPEAKER
9
THERMISTER CONTROL (OPTIONAL)
10
CONTROL
MICROCOMPUTER AND INTERFACE
4
INPUTS
POWER SUPPLY
11
RECHARGEABLE BATTERY
12
DOPPLER DRIVER/RECEIVER
3
DOPPLER TRANSDUCER
2
MAINS POWER
1

FIG. 1

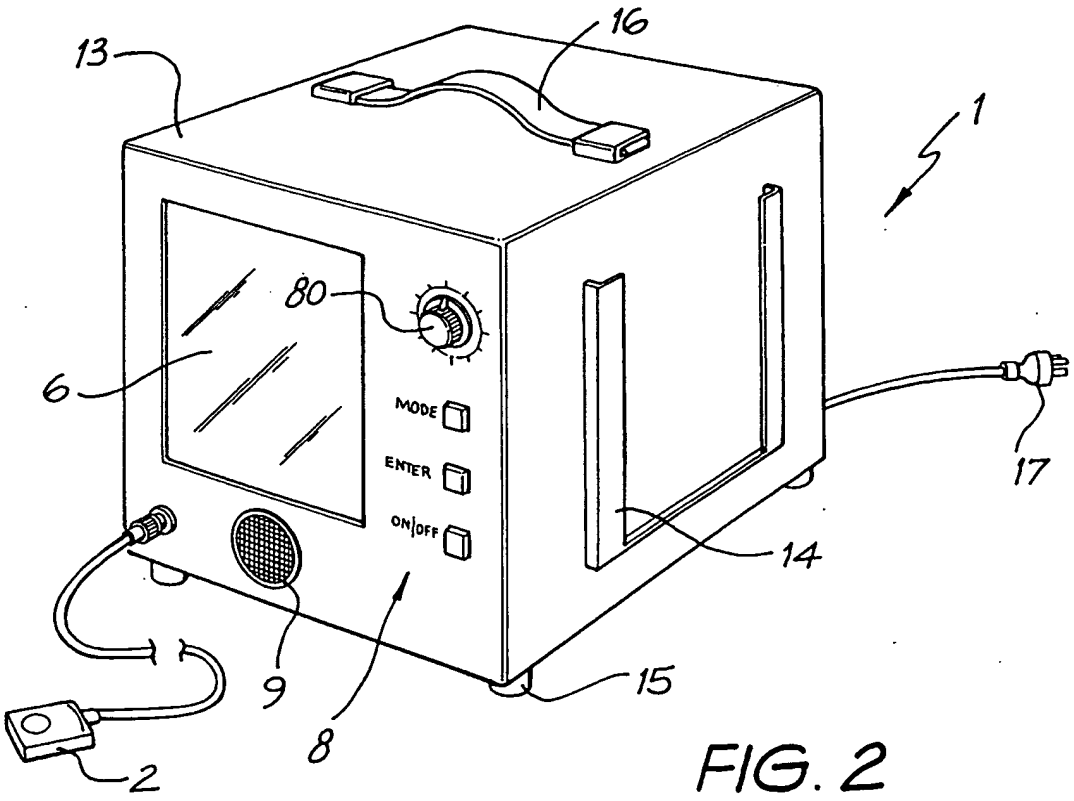
13
16
1
80
6
MODE
ENTER
ON/OFF
17
14
9
8
15
2

FIG. 2

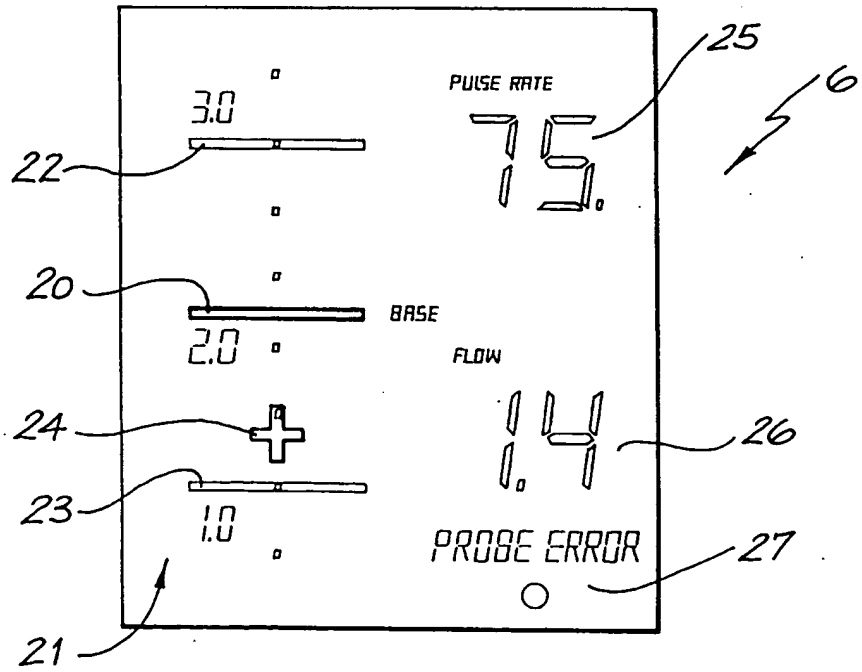
25
6
PULSE RATE
3.0
22
75
20
BASE
2.0
FLOW
24
14
26
23
1.0
PROBE ERROR
27
21

FIG. 3

DISPLAY: DATA ENTRY

PULSE	RATE	DATA
MIN	BASE	MAX
000	300	300
TONE		TONE
OFF		ON
FLOW	RATE	DATA
MIN	BASE	MAX
0.0	9.9	9.9
TONE		TONE
ON		ON

ANIMAL CLASS = NAME OR #

RUN | PAUSE | DATA | CLASS

FIG. 4

DISPLAY: DEFAULT SETTING

ANIMAL CLASS

WEIGHT Kg	SPECIES	#
1-5	CAT/TOY DOG	1
5-10	SMALL DOG	2
10-20	MEDIUM DOG	3
20-40	LARGE DOG	4
30	SHEEP/GOAT	5
150	LLAMA/FOAL	6
450	HORSE	7

AND SLOTS FOR 'MEMORY' ? 5

RUN | PAUSE | DATA | CLASS

FIG. 5

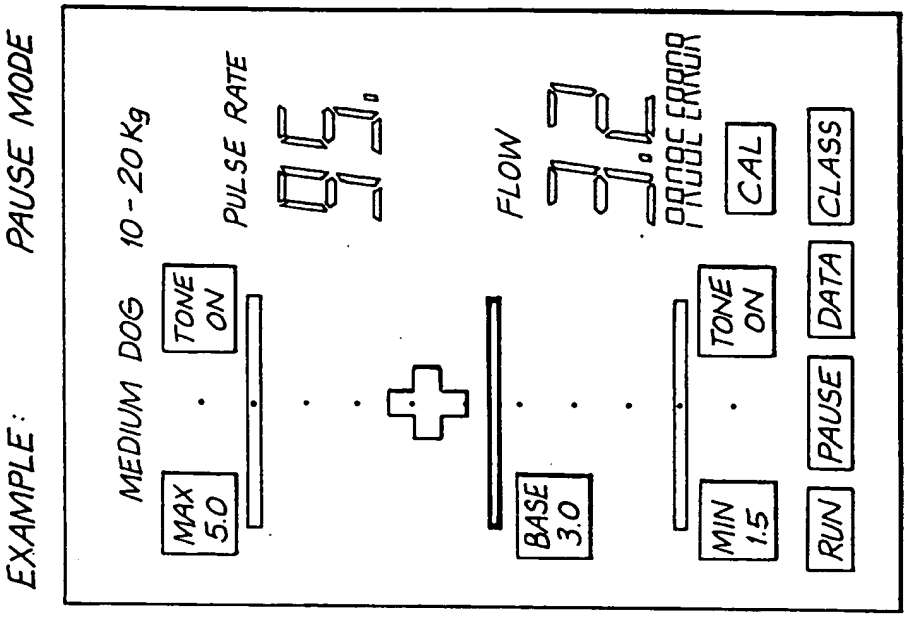
EXAMPLE:
PAUSE MODE
MEDIUM DOG
10 - 20 Kg
MAX 5.0
TONE ON
PULSE RATE
95
FLOW
BASE 3.0
3.7
PROBE ERROR
MIN 1.5
TONE ON
CAL
RUN
PAUSE
DATA
CLASS

FIG. 7

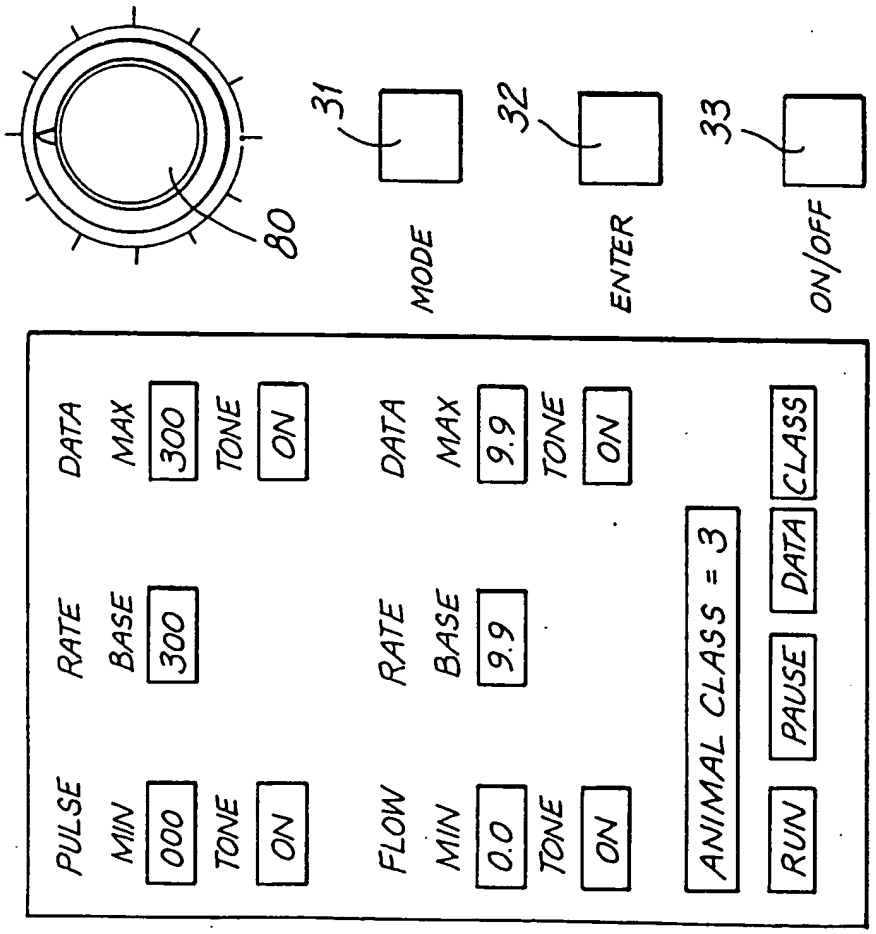
PULSE
MIN
000
TONE
ON
RATE
BASE
300
DATA
MAX
300
TONE
ON
FLOW
MIN
0.0
TONE
ON
RATE
BASE
9.9
DATA
MAX
9.9
TONE
ON
ANIMAL CLASS = 3
RUN
PAUSE
DATA
CLASS
80
31
MODE
32
ENTER
33
ON/OFF

FIG. 6

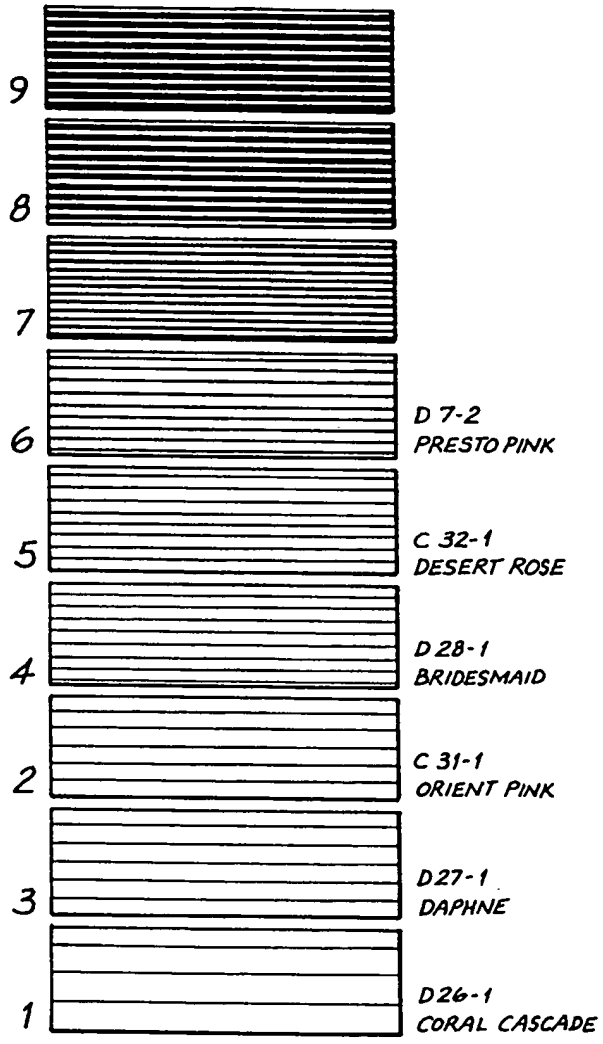
9
8
7
6
D 7-2
PRESTO PINK
5
C 32-1
DESERT ROSE
4
D 28-1
BRIDESMAID
2
C 31-1
ORIENT PINK
3
D 27-1
DAPHNE
1
D 26-1
CORAL CASCADE

FIG. 8

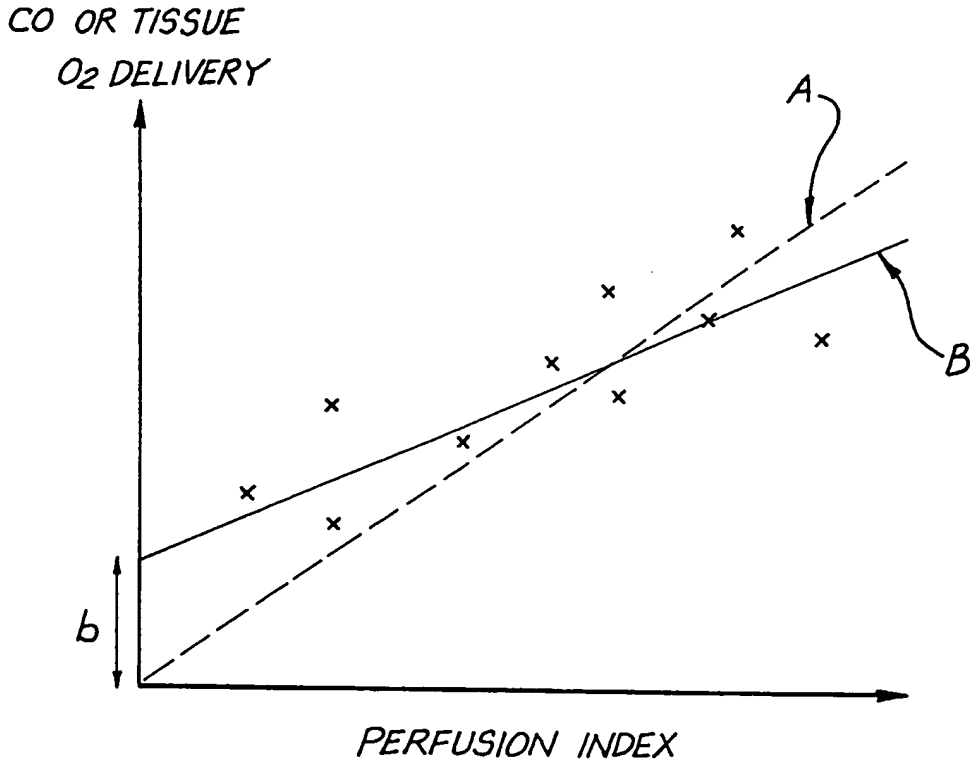

FIG. 9

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 98/00356

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61B 5/026

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: A61B/-; A61D/-; A61M/-

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT and keywords (Blood()flow:, bloodflow, cardiac() output, heart()output, monitor: measur:, determin:, detect:, display:, record:, assess:, anaesthe:, surgery, surgical:, operation, infra()red, infrared)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 86/04225 A1 (APPLIED BIOMETRICS, INC) 31 July 1986 Page 6, line 18-page 8, line 10	1,11,17,24
X	US 5490506 A (TAKATANI et al) 13 February 1996 Column 1, lines 12-23 and line 61-column 2, line 31	1-3,7,17-20,27
X	US 4414980 A (MOTT) 15 November 1983	1-2,12,17-18,25,31

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 August 1998	11 AUG 1998
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929	Authorized officer **GEOFF SADLIER** Telephone No.: (02) 6283 2114

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 98/00356

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96/16594 A2 (HOEFT) 6 June 1996	1,17
X	SU 1364297 A1 (A MED SURGERY) 7 January 1988	1,17,32
X	EP 771546 A2 (OTT) 7 May 1997	1-3,17-19,32-33
X	EP 378234 A1 (TERUMO KABUSHIKI KAISHA) 18 July 1990 Column 7, line 58-column 3, line 17	1,17
X	WO 96/32056 A2 (BILLIET) 17 October 1996	1,17
P,X	WO 97/24980 A1 (CIRCUITRY SYSTEMS LIMITED) 17 July 1997	1,17,31
X	EP 305080 A2 (FRANK et al) 1 March 1989	1-2,17-18,31-33
X	EP 439018 A1 (FEILER) 31 July 1991	1,17,31
X	US 4784150 A (VOORHIES et al) 15 November 1988	1,17,31

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 98/00356

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See attached list.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 98/00356

Box II (continued)

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-30 are directed to a method and device for monitoring haemodynamic function during anaesthesia. It is considered that monitoring blood flow to indicate cardiac output comprises a first "special technical feature".

2. Claim 31 is directed to an infra-red sensor. It is considered that measuring blood flow in a peripheral vessel of a subject comprises a second "special technical feature".

3. Claims 32-33 are directed to a method of monitoring haemodynamic function during stress testing or critical care. It is considered that monitoring changes in blood flow comprises a third "special technical feature".

The feature common to all of the claims is the general monitoring of blood flow. However this common feature is generic in the art. Consequently the common feature does not constitute "a special technical feature" within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art. Since there exists no other common feature which can be considered as a special technical feature within the meaning of PCT Rule 13.2, second sentence, no technical relationship within the meaning of PCT Rule 13 between the different inventions can be seen. Consequently it appears that a posteriori, the claims do not satisfy the requirement of unity of invention.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International Application No.
PCT/AU 98/00356

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	86/04225	EP	208771	US	4671295		
US	5490506	NONE					
US	4414980	NONE					
WO	96/16594	EP	794729				
SU	1364297	NONE					
EP	771546	DE	19630381	EP	728440	DE	19506484
EP	378234	JP	2185232	US	5080106		
WO	96/32056	NONE					
WO	97/24980	AU	11861/97				
EP	305080	NONE					
EP	439018	HK	346/97	US	5375603		
US	4784150	NONE					

END OF ANNEX

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

United States Patent and Trademark Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 07 January 1999 (07.01.99)	
International application No. PCT/AU98/00356	**Applicant's or agent's file reference**
International filing date (day/month/year) 13 May 1998 (13.05.98)	**Priority date** (day/month/year) 13 May 1997 (13.05.97)
Applicant DUNLOP, Colin	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

14 December 1998 (14.12.98)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Athina Nickitas-Etienne
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

GRIFFITH HACK
G.P.O. Box 4164
Sydney, NSW 2001
AUSTRALIE

Date of mailing (day/month/year)	
06 May 1999 (06.05.99)	
Applicant's or agent's file reference	**IMPORTANT NOTIFICATION**
2145357	
International application No.	**International filing date** (day/month/year)
PCT/AU98/00356	13 May 1998 (13.05.98)

1. The following indications appeared on record concerning:

[ ] the applicant [ ] the inventor [X] the agent [ ] the common representative

Name and Address

DAVIES COLLISON CAVE
1 Little Collins Street
Melbourne VIC 3000
Australia

State of Nationality:

State of Residence:

Telephone No.:

Facsimile No.:

Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [X] the name [X] the address [ ] the nationality [ ] the residence

Name and Address

GRIFFITH HACK
G.P.O. Box 4164
Sydney, NSW 2001
Australia

State of Nationality:

State of Residence:

Telephone No.: 02 995 75 944

Facsimile No.: 02 995 76288

Teleprinter No.:

3. Further observations, if necessary:

The receiving Office has informed the International Bureau that the request for change of agent under Rule 92bis was mistakenly sent by the agent. Please disregard form PCT/IB/306 sent 17 March 1999.

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Athina Nickitas-Etienne
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/306 (March 1994)

002607576

PA NT COOPERATION TREAT

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

DAVIES COLLISON CAVE
1 Little Collins Street
Melbourne VIC 3000
AUSTRALIE

Date of mailing (day/month/year)
17 March 1999 (17.03.99)

Applicant's or agent's file reference
2145357

IMPORTANT NOTIFICATION

International application No.
PCT/AU98/00356

International filing date (day/month/year)
13 May 1998 (13.05.98)

1. The following indications appeared on record concerning:

[ ] the applicant [ ] the inventor [X] the agent [ ] the common representative

Name and Address
GRIFFITH HACK
G.P.O. Box 4164
Sydney, NSW 2001
Australia

State of Nationality

State of Residence

Telephone No.
02 99575944

Facsimile No.
02 99576288

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [X] the name [X] the address [ ] the nationality [ ] the residence

Name and Address
DAVIES COLLISON CAVE
1 Little Collins Street
Melbourne VIC 3000
Australia

State of Nationality

State of Residence

Telephone No.

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:
Please amend the reference to read 2145357.

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
Athina Nickitas-Etienne

Telephone No.: (41-22) 338.83.38

Form PCT/IB/306 (March 1994)

002536440

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
Griffith Hack
GPO Box 4164
SYDNEY NSW 2001

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *day/month/year*: 14 SEP 1999

Applicant's or agent's file reference
TJS:JP:FP9678

IMPORTANT NOTIFICATION

International application No.	International filing date	Priority date
PCT/AU 98/00356	13 May 1998	13 May 1997

Applicant
DUNLOP, Colin

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

Name and mailing address of the IPEA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929	GEOFF SADLIER Telephone No. (02) 6283 2114

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference TJS:JP:FP9678	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. **PCT/AU 98/00356**	International filing date *(day/month/year)* 13 May 1998	Priority Date *(day/month/year)* 13 May 1997
International Patent Classification (IPC) or national classification and IPC **Int. Cl.**[6] A61B 5/026		
Applicant DUNLOP, Colin		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 31 sheet(s).

3. This report contains indications relating to the following items:

I	[X]	Basis of the report
II	[ ]	Priority
III	[ ]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[ ]	Lack of unity of invention
V	[X]	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

Date of submission of the demand 14 December 1998	Date of completion of the report 1 September 1999
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. (02) 6285 3929	Authorized Officer **GEOFF SADLIER** Telephone No. (02) 6283 2114

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU 98/00356

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed.

☒ the description, pages , as originally filed,
pages , filed with the demand,
pages 1-26, filed with the letter of 6 August 1999.

☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages 27-30, filed with the letter of 6 August 1999.

☒ the drawings, pages 1/6-6/6, as originally filed,
pages , filed with the demand,
pages , filed with the letter of .

☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , filed with the letter of .

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-32	YES
	Claims		NO
Inventive step (IS)	Claims	1-32	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-32	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The claimed invention relates to a method and apparatus for monitoring haemodynamic function in a human or animal subject, and is intended to avoid the use of blood pressure as an indication of cardiac output.

The solution according to independent claims 1 and 17 involves monitoring changes in blood flow in a peripheral blood vessel to provide an indication of cardiac output.

Documents US 5490506 and EP 771546 are the closest art and each disclose the monitoring of changes in blood flow via a peripheral blood vessel. However these documents do not suggest using the blood flow data to provide an indication of cardiac output. None of the known prior art has recognised a correlation between peripheral blood flow changes and cardiac output.

Therefore the subject matter of the present claims is new and the claims meet the requirements of Article 33(2) PCT with regard to the requirement for novelty. Furthermore the claimed invention is not obvious in the light of any of the cited documents nor disclosed in any obvious combination, nor would the claimed invention be obvious to a person skilled in the art in the light of common general knowledge by itself or in combination with any of these documents.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference TJS:JP:FP9678	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. **PCT/AU 98/00356**	International filing date *(day/month/year)* 13 May 1998	Priority Date *(day/month/year)* 13 May 1997
International Patent Classification (IPC) or national classification and IPC **Int. Cl.**[6] A61B 5/026		
Applicant DUNLOP, Colin		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 31 sheet(s).

3. This report contains indications relating to the following items:

I	[X]	Basis of the report
II	[ ]	Priority
III	[ ]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[ ]	Lack of unity of invention
V	[X]	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

Date of submission of the demand 14 December 1998	Date of completion of the report 1 September 1999
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. (02) 6285 3929	Authorized Officer **GEOFF SADLIER** Telephone No. (02) 6283 2114

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU 98/00356

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed.

☒ the description, pages , as originally filed,
pages , filed with the demand,
pages 1-26, filed with the letter of 6 August 1999.

☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages 27-30, filed with the letter of 6 August 1999.

☒ the drawings, pages 1/6-6/6, as originally filed,
pages , filed with the demand,
pages , filed with the letter of .

☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , filed with the letter of .

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-32	YES
	Claims		NO
Inventive step (IS)	Claims	1-32	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-32	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The claimed invention relates to a method and apparatus for monitoring haemodynamic function in a human or animal subject, and is intended to avoid the use of blood pressure as an indication of cardiac output.

The solution according to independent claims 1 and 17 involves monitoring changes in blood flow in a peripheral blood vessel to provide an indication of cardiac output.

Documents US 5490506 and EP 771546 are the closest art and each disclose the monitoring of changes in blood flow via a peripheral blood vessel. However these documents do not suggest using the blood flow data to provide an indication of cardiac output. None of the known prior art has recognised a correlation between peripheral blood flow changes and cardiac output.

Therefore the subject matter of the present claims is new and the claims meet the requirements of Article 33(2) PCT with regard to the requirement for novelty. Furthermore the claimed invention is not obvious in the light of any of the cited documents nor disclosed in any obvious combination, nor would the claimed invention be obvious to a person skilled in the art in the light of common general knowledge by itself or in combination with any of these documents.

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 98/00356

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61B 5/026

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: A61B/-; A61D/-; A61M/-

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT and keywords (Blood()flow:, bloodflow, cardiac() output, heart()output, monitor: measur:, determin:, detect:, display:, record:, assess:, anaesthe:, surgery, surgical:, operation, infra()red, infrared)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 86/04225 A1 (APPLIED BIOMETRICS, INC) 31 July 1986 Page 6, line 18-page 8, line 10	1,11,17,24
X	US 5490506 A (TAKATANI et al) 13 February 1996 Column 1, lines 12-23 and line 61-column 2, line 31	1-3,7,17-20,27
X	US 4414980 A (MOTT) 15 November 1983	1-2,12,17-18,25,31

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
6 August 1998

Date of mailing of the international search report
11 AUG 1998

Name and mailing address of the ISA/AU
AUSTRALIAN PATENT OFFICE
PO BOX 200
WODEN ACT 2606
AUSTRALIA
Facsimile No.: (02) 6285 3929

Authorized officer
GEOFF SADLIER
Telephone No.: (02) 6283 2114

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 98/00356

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96/16594 A2 (HOEFT) 6 June 1996	1,17
X	SU 1364297 A1 (A MED SURGERY) 7 January 1988	1,17,32
X	EP 771546 A2 (OTT) 7 May 1997	1-3,17-19,32-33
X	EP 378234 A1 (TERUMO KABUSHIKI KAISHA) 18 July 1990 Column 7, line 58-column 3, line 17	1,17
X	WO 96/32056 A2 (BILLIET) 17 October 1996	1,17
P,X	WO 97/24980 A1 (CIRCUITRY SYSTEMS LIMITED) 17 July 1997	1,17,31
X	EP 305080 A2 (FRANK et al) 1 March 1989	1-2,17-18,31-33
X	EP 439018 A1 (FEILER) 31 July 1991	1,17,31
X	US 4784150 A (VOORHIES et al) 15 November 1988	1,17,31

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 98/00356

Box 1 Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See attached list.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Box II (continued)

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-30 are directed to a method and device for monitoring haemodynamic function during anaesthesia. It is considered that monitoring blood flow to indicate cardiac output comprises a first "special technical feature".

2. Claim 31 is directed to an infra-red sensor. It is considered that measuring blood flow in a peripheral vessel of a subject comprises a second "special technical feature".

3. Claims 32-33 are directed to a method of monitoring haemodynamic function during stress testing or critical care. It is considered that monitoring changes in blood flow comprises a third "special technical feature".

The feature common to all of the claims is the general monitoring of blood flow. However this common feature is generic in the art. Consequently the common feature does not constitute "a special technical feature" within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art. Since there exists no other common feature which can be considered as a special technical feature within the meaning of PCT Rule 13.2, second sentence, no technical relationship within the meaning of PCT Rule 13 between the different inventions can be seen. Consequently it appears that a posteriori, the claims do not satisfy the requirement of unity of invention.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.
PCT/AU 98/00356

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	86/04225	EP	208771	US	4671295		
US	5490506	NONE					
US	4414980	NONE					
WO	96/16594	EP	794729				
SU	1364297	NONE					
EP	771546	DE	19630381	EP	728440	DE	19506484
EP	378234	JP	2185232	US	5080106		
WO	96/32056	NONE					
WO	97/24980	AU	11861/97				
EP	305080	NONE					
EP	439018	HK	346/97	US	5375603		
US	4784150	NONE					

END OF ANNEX

WO 98/51212
PCT/AU98/0035

PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

To:
GRIFFITH HACK
G.P.O. Box 4164
Sydney, NSW 2001
AUSTRALIE

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

Date of mailing (day/month/year) 19 November 1998 (19.11.98)	
Applicant's or agent's file reference TDS IFP9678	IMPORTANT NOTICE

International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/AU98/00356	13 May 1998 (13.05.98)	13 May 1997 (13.05.97)

Applicant
DUNLOP, Colin

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
   AU,BR,CA,CN,EP,IL,JP,KP,KR,NO,PL,US

   In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
   AL,AM,AP,AT,AZ,BA,BB,BG,BY,CH,CU,CZ,DE,DK,EA,EE,ES,FI,GB,GE,GH,GM,GW,HU,ID,IS,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MD,MG,MK,MN,MW,MX,NZ,OA,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,UA,UG,UZ,VN,YU,ZW
   The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
   19 November 1998 (19.11.98) under No. WO 98/51212

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer J. Zahra
Facsimile No. (41-22) 740.14.35	Telephone No. (41-22) 338.83.38

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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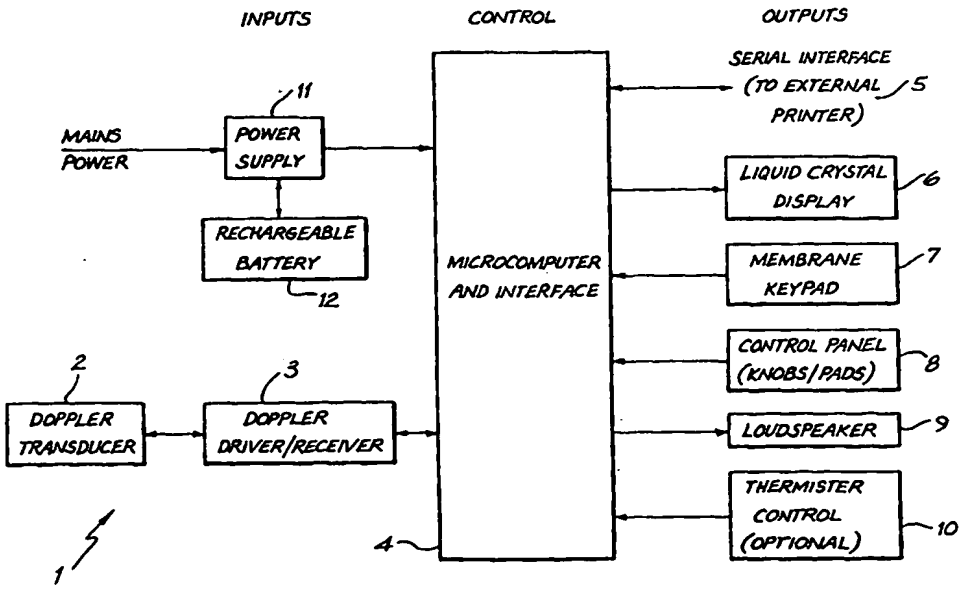
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: METHOD AND APPARATUS FOR MONITORING HAEMODYNAMIC FUNCTION



(57) Abstract

The present invention relates to a method and apparatus for monitoring haemodynamic function in animals and humans during anaesthesia and surgery. During anaesthesia and surgery the subject's haemodynamic, respiratory, neuromuscular and neurological functions are monitored as indicators of the condition of the health of the subject. Commonly, variations in blood pressure are used to imply corresponding variations in cardiac ouput, i.e. good blood pressure equals good cardiac output. The present invention utilises a device to monitor changes of blood flow in peripheral blood vessels of the subject as an indicator of cardiac output. This is believed to provide a much more accurate indicator.

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REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No. PCT/AU 98 / 00356

13 MAY 1998 (13.5.98)

International Filing Date

Australian Patent Office
PCT INTERNATIONAL APPLICATION

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference _
(if desired) (12 characters maximum)

Box No. I TITLE OF INVENTION

METHOD AND APPARATUS FOR MONITORING HAEMODYNAMIC FUNCTION

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)*

DUNLOP, COLIN
6 GANORA STREET
GLADESVILLE NSW 2111
AUSTRALIA

☒ This person is also inventor.

Telephone No. (02) 9816 3282

Facsimile No. (02) 9816 2592

Teleprinter No.

State *(i.e. country)* of nationality: AUSTRALIA

State *(i.e. country)* of residence: AUSTRALIA

This person is applicant for the purposes of: ☒ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)*

This person is:

☐ applicant only

☐ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(i.e. country)* of nationality:

State *(i.e. country)* of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

GRIFFITH HACK
GPO BOX 4164
SYDNEY NSW 2001
AUSTRALIA

Telephone No. (02) 99575444

Facsimile No. (02) 94576288

Teleprinter No.

☐ Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

▲ INSERTED RO/AU

See Notes to the request form

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes; at least one must be marked)*:

Regional Patent

- ☒ AP **ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ EA **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ EP **European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ OA **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

- ☒ AL Albania .....
- ☒ AM Armenia .....
- ☒ AT Austria .....
- ☒ AU Australia .....
- ☒ AZ Azerbaijan
- ☒ BA Bosnia and Herzegovina .....
- ☒ BB Barbados
- ☒ BG Bulgaria .....
- ☒ BR Brazil .....
- ☒ BY Belarus
- ☒ CA Canada
- ☒ CH and LI Switzerland and Liechtenstein
- ☒ CN China .....
- ☒ CU Cuba .....
- ☒ CZ Czech Republic .....
- ☒ DE Germany .....
- ☒ DK Denmark .....
- ☒ EE Estonia .....
- ☒ ES Spain .....
- ☒ FI Finland .....
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- ☒ GH Ghana .....
- ☒ GM Gambia
- ☒ GW Guinea-Bissau .....
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- ☒ IL Israel .....
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- ☒ JP Japan .....
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- ☒ KP Democratic People's Republic of Korea .....
- ☒ KR Republic of Korea .....
- ☒ KZ Kazakhstan .....
- ☒ LC Saint Lucia
- ☒ LK Sri Lanka
- ☒ LR Liberia
- ☒ LS Lesotho .....
- ☒ LT Lithuania
- ☒ LU Luxembourg
- ☒ LV Latvia
- ☒ MD Republic of Moldova .....
- ☒ MG Madagascar .....
- ☒ MK The former Yugoslav Republic of Macedonia .....
- ☒ MN Mongolia
- ☒ MW Malawi .....
- ☒ MX Mexico .....
- ☒ NO Norway
- ☒ NZ New Zealand .....
- ☒ PL Poland .....
- ☒ PT Portugal .....
- ☒ RO Romania
- ☒ RU Russian Federation .....
- ☒ SD Sudan
- ☒ SE Sweden
- ☒ SG Singapore
- ☒ SI Slovenia .....
- ☒ SK Slovakia .....
- ☒ SL Sierra Leone
- ☒ TJ Tajikistan .....
- ☒ TM Turkmenistan .....
- ☒ TR Turkey .....
- ☒ TT Trinidad and Tobago .....
- ☒ UA Ukraine .....
- ☒ UG Uganda .....
- ☒ US United States of America .....
- ☒ UZ Uzbekistan .....
- ☒ VN Viet Nam .....
- ☒ YU Yugoslavia .....
- ☒ ZW Zimbabwe .....

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

- ☐ .....
- ☐ .....
- ☐ .....

In addition to the designations made above, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except the designation(s) of _____.

The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM Further priority claims are indicated in the Supplemental Box ☐

The priority of the following earlier application(s) is hereby claimed:

Country (in which, or for which, the application was filed)	Filing Date (day/month/year)	Application No.	Office of filing (only for regional or international application)
item (1) AUSTRALIA	13 MAY 1997 (13/05/1997)	PO6763	
item (2)			
item (3)			

Mark the following check-box if the certified copy of the earlier application is to be issued by the Office which for the purposes of the present international application is the receiving Office (a fee may be required):

☒ The receiving Office is hereby requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s) : _____

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):* ISA / _____

Earlier search *Fill in where a search (international, international-type or other) by the International Searching Authority has already been carried out or requested and the Authority is now requested to base the international search, to the extent possible, on the results of that earlier search. Identify such search or request either by reference to the relevant application (or the translation thereof) or by reference to the search request:*

Country (or regional Office): Date *(day/month/year)*: Number:

Box No. VIII CHECK LIST

This international application contains the following number of sheets:

1. request	: 3	sheets
2. description	: 27	sheets
3. claims	: 4	sheets
4. abstract	: 1	sheets
5. drawings	: 6	sheets
Total	: 41	sheets

This international application is accompanied by the item(s) marked below:

1. ☐ separate signed power of attorney
2. ☐ copy of general power of attorney
3. ☐ statement explaining lack of signature
4. ☐ priority document(s) *identified in Box No. VI as item(s):*
5. ☑ fee calculation sheet
6. ☐ separate indications concerning deposited microorganisms
7. ☐ nucleotide and/or amino acid sequence listing (diskette)
8. ☐ other *(specify)*:

Figure No. 1 of the drawings (if any) should accompany the abstract when it is published.

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

TIM STACEY. GRIFFITH HACK (AGENT).

For receiving Office use only

1. Date of actual receipt of the purported international application: 13 MAY 1998 (13.5.98)
2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority specified by the applicant: ISA /
6. ☐ Transmittal of search copy delayed until search fee is paid

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

[redacted]TENT COOPERATION TREA[redacted]

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference TJS:JP:FP9678	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. **PCT/AU 98/00356**	International filing date *(day/month/year)* 13 May 1998	Priority Date *(day/month/year)* 13 May 1997
International Patent Classification (IPC) or national classification and IPC **Int. Cl.**[6] A61B 5/026		
Applicant DUNLOP, Colin		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 31 sheet(s).

3. This report contains indications relating to the following items:

I	[X]	Basis of the report
II	[ ]	Priority
III	[ ]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[ ]	Lack of unity of invention
V	[X]	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
14 December 1998	1 September 1999
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. (02) 6285 3929	Authorized Officer **GEOFF SADLIER** Telephone No. (02) 6283 2114

INTERNATIONAL PRE[redacted]ARY EXAMINATION REPORT

[redacted]ernational application No.
PCT/AU 98/00356

I. Basis of the report

1. With regard to the **elements** of the international application:*

- [ ] the international application as originally filed.
- [X] the description, pages , as originally filed,
  pages , filed with the demand,
  pages **1-26,** filed with the letter of **6 August 1999.**
- [X] the claims, pages , as originally filed,
  pages , as amended (together with any statement) under Article 19,
  pages , filed with the demand,
  pages **27-30,** filed with the letter of **6 August 1999.**
- [X] the drawings, pages **1/6-6/6,** as originally filed,
  pages , filed with the demand,
  pages , filed with the letter of .
- [ ] the sequence listing part of the description:
  pages , as originally filed
  pages , filed with the demand
  pages , filed with the letter of .

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [ ] the language of publication of the international application (under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

- [ ] contained in the international application in written form.
- [ ] filed together with the international application in computer readable form.
- [ ] furnished subsequently to this Authority in written form.
- [ ] furnished subsequently to this Authority in computer readable form.
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:
   - [ ] the description, pages
   - [ ] the claims, Nos.
   - [ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-32	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	1-32	**YES**
	Claims		**NO**
Industrial applicability (IA)	Claims	1-32	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

The claimed invention relates to a method and apparatus for monitoring haemodynamic function in a human or animal subject, and is intended to avoid the use of blood pressure as an indication of cardiac output.

The solution according to independent claims 1 and 17 involves monitoring changes in blood flow in a peripheral blood vessel to provide an indication of cardiac output.

Documents US 5490506 and EP 771546 are the closest art and each disclose the monitoring of changes in blood flow via a peripheral blood vessel. However these documents do not suggest using the blood flow data to provide an indication of cardiac output. None of the known prior art has recognised a correlation between peripheral blood flow changes and cardiac output.

Therefore the subject matter of the present claims is new and the claims meet the requirements of Article 33(2) PCT with regard to the requirement for novelty. Furthermore the claimed invention is not obvious in the light of any of the cited documents nor disclosed in any obvious combination, nor would the claimed invention be obvious to a person skilled in the art in the light of common general knowledge by itself or in combination with any of these documents.